

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method of administering diazepam to a mammal comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition for transmucosal administration of diazepam or a pharmaceutically acceptable salt thereof comprising:

diazepam or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a polar solvent in an amount between 30 and 99.69 percent by weight of the total composition.

2. (Currently amended) The ~~composition~~ method of claim 1, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

3. (Currently amended) The ~~composition~~ method of claim 2, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the diazepam or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

4. (Currently amended) The ~~composition~~ method of claim 3, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the diazepam or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the

taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

5. (Currently amended) The ~~composition~~ method of claim 1, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C₂ to C₁₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration.

6. (Currently amended) The ~~composition~~ method of claim 1, wherein the polar solvent comprises polyethylene glycol.

7. (Currently amended) The ~~composition~~ method of claim 1, wherein the polar solvent comprises ethanol.

8. (Currently amended) The ~~composition~~ method of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

9. (Canceled).

10. (Currently amended) The method of claim ~~[[9]]~~1, wherein the amount of the spray is predetermined.

Claims 11-21 (Canceled).

22. (Currently amended) A method of administering diazepam to a mammal comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition for transmucosal administration of diazepam or a pharmaceutically acceptable salt thereof comprising:

diazepam or a pharmaceutically acceptable salt thereof in an amount between 0.005 and 55 percent by weight of the total composition; and

a non-polar solvent in an amount between 30 and 99.69 percent by weight of the total composition.

23. (Currently amended) The ~~composition~~ method of claim 22, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

24. (Currently amended) The ~~composition~~ method of claim 23, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

25. (Currently amended) The ~~composition~~ method of claim 22, wherein the solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

26. (Currently amended) The ~~composition~~ method of claim 25, wherein the solvent is a triglyceride.

27. (Canceled).

28. (Currently amended) The method of claim ~~[[27]]~~ 22, wherein the amount of the spray is predetermined.

Claims 29-40 (Canceled).

41. (Currently amended) A method of administering diazepam to a mammal comprising spraying the oral mucosa of the mammal with a propellant free buccal

spray composition for ~~transmucosal administration of diazepam or a pharmaceutically acceptable salt thereof~~ comprising:

diazepam or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1.

42. (Currently amended) The ~~composition~~ method of claim ~~[[40]]~~41, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

43. (Currently amended) The ~~composition~~ method of claim 42, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the diazepam or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

44. (Currently amended) The ~~composition~~ method of claim 43, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the diazepam or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

45. (Currently amended) The ~~composition~~ method of claim 41, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a

molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

46. (Currently amended) The ~~composition~~ method of claim 42, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

47. (Canceled).

48. (Currently amended) The method of claim ~~[[47]]~~41, wherein the amount of the spray is predetermined.

Claims 49-56 (Canceled).

57. (Currently amended) ~~[[A]]~~The method of claim 1, further comprising managing anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 1~~.

58. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising administering anesthesia to a patient, comprising pre-medicating the patient with diazepam before administering the anesthesia comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 1~~.

59. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising relieving muscle spasms in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 1~~.

60. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising treating status epilepticus in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 1~~.

61. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising treating the symptoms of acute alcohol ~~withdrawal~~ withdrawal in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 1~~.

62. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising treating intoxication from exposure to an anticholinesterase agent in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 1~~.

63. (Withdrawn) The method of claim 62, wherein the anticholinesterase agent is a nerve gas.

Claims 64-70 (Canceled).

71. (Currently amended) ~~[[A]]~~The method of claim 1, further comprising managing anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 22~~.

72. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising administering anesthesia to a patient, comprising pre-medicating the patient with diazepam before administering the anesthesia comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 22~~.

73. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising relieving muscle spasms in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 22.~~

74. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising treating status epilepticus in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 22.~~

75. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising treating the symptoms of acute alcohol ~~withdrawal~~ withdrawal in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 22.~~

76. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising treating intoxication from exposure to an anticholinesterase agent in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 22.~~

77. (Withdrawn) The method of claim 76, wherein the anticholinesterase agent is a nerve gas.

Claims 78-84 (Canceled).

85. (Currently amended) ~~[[A]]~~The method of claim 1, further comprising managing anxiety in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 41.~~

86. (Withdrawn and currently amended) ~~[[A]]~~The method of claim 1, further comprising administering anesthesia to a patient ~~[[.]]~~comprising pre-medicating the patient with diazepam before administering the anesthesia comprising spraying the

oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 41.~~

87. (Withdrawn and currently amended) ~~[[A]]~~ The method of claim 1, further comprising relieving muscle spasms in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 41.~~

88. (Withdrawn and currently amended) ~~[[A]]~~ The method of claim 1, further comprising treating status epilepticus in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 41.~~

89. (Withdrawn and currently amended) ~~[[A]]~~ The method of claim 1, further comprising treating the symptoms of acute alcohol ~~withdrawal~~ withdrawal in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 41.~~

90. (Withdrawn and currently amended) ~~[[A]]~~ The method of claim 1, further comprising treating intoxication from exposure to an anticholinesterase agent in a patient, comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray ~~of claim 41.~~

91. (Withdrawn) The method of claim 90, wherein the anticholinesterase agent is a nerve gas.

Claims 92-98 (Canceled).